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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,369	05/15/2006	Jeffrey B. Stock	2008725-0051	3055
24280 7590 02/10/2009 CHOATE, HALL & STEWART LLP TWO INTERNATIONAL PLACE BOSTON, MA 02110				
EXAMINER				
GITOMER, RALPH J				
ART UNIT		PAPER NUMBER		
1657				
NOTIFICATION DATE		DELIVERY MODE		
02/10/2009		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@choate.com

Office Action Summary

Application No.

10/579,369

Applicant(s)

STOCK ET AL.

Examiner

Ralph Gitomer

Art Unit

1657

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-8 and 10-21 is/are pending in the application.
- 4a) Of the above claim(s) 12-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S508)
- Paper No(s)/Mail Date 8/22/08
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

The amendment received 12/30/08 has been entered and claims 1, 3-8, 10, 11, 17-21 are considered here. The IDS received 8/22/08 has been considered.

In view of the amendments to the claims and arguments presented, the rejections of record under 35 USC 112, first paragraph, are hereby withdrawn.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 6-8, 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee.

Lee (PNAS) entitled "A Specific Protein Carboxyl Methyltransferase That Demethylates Phosphoprotein Phosphatase 2A in Bovine Brain" teaches on page 6044 column 1 last full paragraph, identifying a compound that is responsible for demethylation of PP2A is described. On page 6046 Fig. 4 shows inhibition of demethylation reaction of PP2A by a compound identified.

All the features of the claims are taught by Lee for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 5, 10, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Lee in view of Roder.

See the teachings of Lee above.

The claims differ from Lee in that they specify the protein activity is phosphorylation of tau which is hyperphosphorylated and the compound modulates methylation of PP2A and thereby decreases tau hyperphosphorylation.

Roder (6,541,468) entitled "Indolocarbazole Derivatives Useful for the Treatment of Neurodegenerative Diseases and Cancer" teaches in column 1 lines 49-54, it is desirable to have a pharmaceutical means to interfere with the pathological process of

tau hyperphosphorylation. In column 2 first paragraph the most convincing cellular models involve PP2A inhibition.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modulate the activity of PP2A by demethylating the enzyme as taught by Lee and thereby reduce hyperphosphorylation of tau because Roder teaches the relationship between PP2A activity and pathological tau hyperphosphorylation. Further, modulating the activity of PP2A by any means, such as methylation as taught by Lee, would then inherently change the tau phosphorylation. No new pathways are taught.

Applicant's arguments filed 12/30/08 have been fully considered but they are not persuasive.

Applicants response argues that Lee does not teach a plurality of test agents as in claims 1 and 3 nor PP2A plus either a methylase or demethylase enzyme as in claim 6. And in new claims 17, 20 and 21 the test agents affect the activity of the enzyme. Claims 3 and 19 are directed to modulators of the phosphorylation status of a phosphorylated protein (tau). Roder is directed to kinases, not phosphatases.

It is the examiner's position that Lee teaches on page 6045 column 1 first paragraph, different compounds at different concentrations of inhibitors are shown. The assay taught by Lee contains both PP2A and a methylase enzyme where the test agents affect the enzyme activity. Roder was cited to show the connection or pathway between PP2A and tau.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-8, 10, 11, 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

In claim 1 and all occurrences, the preamble of the claim is directed to "identifying agents" but the claim lacks any such step. In claims 17 and 18, "the PP2A methylation assay" lacks antecedent basis. In claim 19 the preamble is directed to compositions but the steps are directed to "candidate test agents" and "the composition".

The title of the invention is not descriptive where no systems are claimed. A new title is required that is clearly indicative of the invention to which the claims are directed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ralph Gitomer/
Primary Examiner, Art Unit 1657

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Primary Examiner
Art Unit 1657

Application/Control Number: 10/579,369
Art Unit: 1657

Page 7